

REMARKS

This application is a broadening reissue application that was filed within two years of the issue date of U.S. Patent No. 6,264,659. Claims 1-24 are now pending. Claims 1, 12-17 and 19-22 have been amended. Original claims 2-11 and 18 remain unchanged. New claims 23 and 24 have been added. This Amendment is a supplemental response to a telephone interview with the Examiner, who indicated that the proposed amendments to the claims failed to comply with 37 CFR 1.173(b). The aforementioned amendments were submitted in a preliminary amendment filed July 24, 2003, submitted with the reissue application. The new claims do not recapture subject matter surrendered during prosecution of U.S. Patent No. 6,264,659.

Telephone Interview

On May 24, 2006, the Examiner telephoned the undersigned Attorney and indicated that the Applicant's preliminary amendment submitted July 24, 2003 was defective because it did not comply with 37 CFR 1.173. Thus, the Examiner requested a supplemental amendment to address the aforementioned defects.

All claim amendments, including new claims, have been made with markings showing changes relative to the issued patent as required by 37 CFR 1.173(d)&(g).

Claim Status

Claims 1-24 are now pending. Claims 1, 12-17 and 19-22 have been amended. Original claims 2-11 and 18 remain unchanged. New claims 23 and 24 have been added. The status of the pending claims is as follows.

CLAIM	STATUS
1	Amended
2-11	Unchanged
12-17	Amended
18	Unchanged
19-22	Amended
23-24	New

Explanations For Amendments To Claims

The support in the disclosure of U.S. Patent No. 6,264,659 for the changes made to the claims (*i.e.*, amended claims 1, 12-17 and 19-22 and new claims 23-24) is found in at least the following sections of the '659 patent set forth below under the respective claim(s).

Claim 1 has been amended as follows:

1. A process of replacing nucleus pulposus of an intervertebral disk, comprising:
 [identifying a location of a rupture in an annulus fibrosus of an intervertebral disk;]
 removing nucleus pulposus associated with [said] an annulus fibrosus of [said] an intervertebral disk; and
 injecting a thermoplastic material heated to a temperature over 50 C. for flowing into said annulus fibrosus and then permitting said material to cool for setting in a non-flowing state upon reaching a temperature of between 35 C. and 42C., so as to cause said material to occupy a space formerly occupied by said removed nucleus pulposus.

Line No.	Support For Amendment
4	Figure 3 (nucleus pulposus removed from areas adjacent to the rupture, aperture or hole 14, as well as the interior away from said rupture, aperture or hole 14). Column 1, lines 30-35 (annulus fibrosus may be accessed via tear, puncture, rupture or prolapse). Column 1, lines 43-45 (disk site may be surgically accessed).

Claim 12 has been amended as follows:

12. [The] An injection device [as defined in claim 4] for injecting thermoplastic material, the injection device comprising:

a heating element and a needle for dispensing of the thermoplastic material into an intervertebral disk [wherein the thermoplastic material comprises a geometric isomer of natural rubber].

Line No.	Support For Amendment
1-3	<p>Figure 3 (injection device 22 with needle 38 and heater 28 dispensing thermoplastic material 20).</p> <p>Column 2, lines 12-15 (injection of a thermoplastic material heated to a predetermined temperature for injection into the nucleus pulposus in a flowable state).</p> <p>Column 2, lines 61-67 (an injection device utilized for heating and injecting the thermoplastic material, the device may utilize a silver needle encased in ceramics).</p> <p>Column 4, lines 53-56 (a heater 28 is provided to heat the thermoplastic material).</p>

Claim 13 has been amended as follows:

13. The injection device as defined in claim [4] 12, wherein said [heater] heating element heats said thermoplastic material for flowing at a temperature between about 150C and 200C.

Line No.	Support For Amendment
1-2	<p>Figure 3 (showing a heating element 28 provided to heat the thermoplastic material).</p> <p>Column 4, lines 53-56 (a heater 28 is provided to heat the thermoplastic material).</p>
2-3	<p>Column 5, lines 21-27 (Generally the lowest temperature to which the thermoplastic material is heated while utilizing a large diameter needle such as 1 centimeter in diameter with a relatively high axial force may be 50 C, while the highest temperature will be less than about 250 C. The optimum temperature is about 185 C, within an optimum range between about 150 C and 200 C).</p>

Claim 14 has been amended as follows:

14. The injection device as defined in claim [4] 12, wherein said thermoplastic material comprises a linear crystalline polymer.

Line No.	Support For Amendment
1-2	Column 2, lines 25-30 (A thermoplastic material which has been found to be highly satisfactory is gutta percha which is normally combined with other elements or ingredients in a suitable gutta percha compound. Gutta percha is a linear crystalline polymer which melts at a predetermined temperature, and a random but distinct change in structure results).

Claim 15 has been amended as follows:

15. The injection device as defined in claim [4] 12, wherein said thermoplastic material comprises a gutta percha compound in which gutta percha is between 15% and 40% by weight of the compound.

Line No.	Support For Amendment
1-3	Column 2, lines 25-30 (A thermoplastic material which has been found to be highly satisfactory is gutta percha which is normally combined with other elements or ingredients in a suitable gutta percha compound. Gutta percha is a linear crystalline polymer which melts at a predetermined temperature, and a random but distinct change in structure results.) Column 2, lines 45-52 (A suitable gutta percha compound is dental gutta percha which contains by weight only about 20% gutta percha with zinc oxide comprising about 60% to 75% of the material. The remaining 5% to 10% consists of various resins, waxes, and metal sulfates. The percentages listed are directed to an optimum gutta percha compound. The preferred percentage of gutta percha is in the range of 15% to 40%).

Claim 16 has been amended as follows:

16. The injection device as defined in claim [4] 12, wherein said injection needle is formed of a ceramic material.

Line No.	Support For Amendment
1-2	Figure 3 (an injection needle 38 preferably formed of silver extends from body 24 and has a ceramic sheath 40 about a portion of needle 38). Column 2, lines 63-66 (The injection device may utilize a silver needle, encased in ceramics, of about 20 to 30 centimeters in length with a diameter as high as 1 centimeter).

Claim 17 has been amended as follows:

17. The injection device as defined in claim [4] 12, further comprising:
an expandable sleeve about said needle adjacent an extending end of said needle to define
an annulus between said needle and said sleeve, so that pressurized fluid communicating with the
annulus expands said sleeve outwardly.

Line No.	Support For Amendment
1-3	Figure 7 (a detachable balloon dilator sleeve 106 extends about the extending end of needle 104 having lateral openings 107).
4-5	Figure 7 (Piston 108 is effective to pressurize the fluid for flow through openings 107 for expansion of sleeve 106 as shown in broken lines in FIG. 7. Dilator sleeve 106 upon injection of needle 104 in a disk of the spine is expanded for exerting an expanding force against the disk).

Claim 19 has been amended as follows:

19. The injection device as defined in claim [4] 12, further comprising:
a chamber for receiving a plug of said thermoplastic material;
a piston adjacent an end of said plug for exerting a force against said plug; and
a hand operated trigger [is] operatively connected to said piston and upon actuation is
effective to force said thermoplastic material from said needle when said thermoplastic material
is heated to a flowing state.

Line No.	Support For Amendment
1-3	<p>Figure 3 (injection gun 22 has a body 24 with removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20).</p> <p>Figure 6 (a generally cylindrical chamber or housing 72 adjacent heater 64 is provided to receive a cylindrical plug 74 of the thermoplastic material).</p> <p>Column 4, lines 51-53 (injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20).</p> <p>Column 6, lines 13-15 (a generally cylindrical chamber or housing 72 adjacent heater 64 is provided to receive a cylindrical plug 74 of the thermoplastic material).</p>
4	<p>Figure 7 (a piston for pressurizing the fluid).</p> <p>Column 6, lines 56-59 (a disk dilator assembly generally indicated at 100 having a cylindrical chamber 102 with an inert fluid such as saline therein and a piston 108 for pressurizing the fluid).</p>
5-7	<p>Figure 3 (a hand operated trigger for activating a force).</p> <p>Column 4, lines 59-62 (a hand operated trigger 42 may be activated for forcing thermoplastic material 20 from the end of needle 38 upon heating of the thermoplastic material 20 to a predetermined temperature).</p>

Claim 20 has been amended as follows:

20. The injection device as defined in claim [4] 12, further comprising[;]:
a chamber for receiving a plug of said thermoplastic material; and
a hand operated trigger operatively connected to said plug thermoplastic material and
upon actuation is effective to force said thermoplastic material from said needle when said
thermoplastic material is heated to a flowing state.

Line No.	Support For Amendment
1-3	Figure 3 (injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20). Figure 6, (a generally cylindrical chamber or housing 72 adjacent heater 64 is provided to receive a cylindrical plug of the thermoplastic material 20). Column 4, line 51-53 (injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20). Column 6, lines 13-15 (a generally cylindrical chamber or housing 72 adjacent heater 64 is provided to receive a cylindrical plug 74 of the thermoplastic material).
4-6	Figure 3 (a hand operated trigger for activating a force). Column 4, lines 59-62 (a hand operated trigger 42 may be activated for forcing thermoplastic material 20 from the end of needle e38 upon heating of the thermoplastic material 20 to a predetermined temperature).

Claim 21 has been amended as follows:

21. The injection device as defined in claim [4] 20, [further comprising;] wherein:
[the] said chamber for receiving [the] said plug is provided in a plunger removable from an injection device body.

Line No.	Support For Amendment
4	Figure 3 & Column 4 lines 48-50 (injection of thermoplastic material 20 within the annulus fibrosus 12 by an injection device or gun illustrated schematically at 22 is shown. Injection gun 22 has a body 24 with a removable plunger 26 adapted to receive a cylindrical plug of the thermoplastic material 20). Column 2, line 66 – Column 3, line 4 (The size of the needle may depend on such factors as the amount of thermoplastic material to be injected, the temperature of the thermoplastic being injected, and the axial pressure applied by the injection device, such as a piston or plunger, to the thermoplastic material to force the heated material from the end of the needle into the spine).

Claim 22 has been amended as follows:

22. The injection device [asa] as defined in claim [4] 12, further comprising[;]:
 a heater control unit having an adjustable temperature control to provide a selected temperature for said [heater] heating element.

Line No.	Support For Amendment
1	Column 2, lines 61-67 (an injection device utilized for heating and injecting the thermoplastic material, the device may utilize a silver needle encased in ceramics).
3-4	Figure 3 and Column 4, lines 53-56 (a heater 28 is provided to heat the thermoplastic material 20 and a heater control unit 30 having an adjustable temperature control knob 32 is provided with a temperature readout at 34).

New claims 23-24 find support as follows:

Claim No.	Support For Addition
23	Column 2, lines 28-29 (gutta percha is a linear crystalline polymer which melts at a predetermined temperature, and a random but distinct change in structure results).
24	Column 2, line 12-17 (the present invention is particularly directed to a process for treating the spine including the injection of a thermoplastic material heated to a predetermined temperature for injection into the nucleus pulposus in a flowing state where it cools and sets at body temperature into a non-flowing state). Column 2, lines 61-63 (an injection device, such as an injection gun, is utilized for heating and injecting the thermoplastic material under a predetermined pressure within the spine). Column 4, line 48 – Column 5, line 27 (description of use of device to heat thermoplastic material and inject into annulus fibrosus to cool to form a resilient cushion).

CONCLUSION

The foregoing amendments have been submitted to place the present application in condition for allowance. Favorable consideration and allowance of the claims in this application is respectfully requested. In the event that there are any questions concerning this Amendment or the application in general, the Examiner is cordially invited to telephone the undersigned attorney so that prosecution may be expedited.

Respectfully submitted,
NUVASIVE, INC.

By:


Jonathan Spangler, Esq.
Registration No. 40,182

4545 Towne Centre Court
San Diego, CA 92121
Tel.: (858) 243-0029
Fax: (858) 909-2007

Date: May 24, 2006